

Application No. 10/805,816  
Amendment dated January 20, 2006  
Reply to Office Action dated September 23, 2005

### **REMARKS/ARGUMENTS**

The Office Action dated September 23, 2005, has been reviewed in detail and the claims have been amended in the sincere effort to place the same in condition for allowance, or in better condition for consideration on appeal.

Applicant retains the right to pursue broader claims via a continuing application under 35 U.S.C. § 120.

#### **Rejection Claims 1-5 and 8-12 under 35 U.S.C. §102:**

The Examiner has rejected Claims 1-5 and 8-12 under 35 U.S.C. § 102 at being anticipated by Davis et al. Specifically the Examiner stated:

Davis teaches in paragraphs [84], [90], [92], [102], [106], [134], and in Figs. 1, 8, 10, and 14, a process for measuring pressure buildup in one or more body compartments that encases muscular tissue (blood vessel network) comprising the steps of assessing a body compartment configuration; and identifying the effect of pulsatile components on at least one dimension of the body component. Davis further teaches that the pressure measurement means is an ultrasound transducer which inherently includes broadband transmit/receive capability in order to determine the compartment boundary and configuration of the blood vessel network.

It is respectfully submitted that the Davis reference does not anticipate the present invention. The Davis reference provides means and methods for gathering physiological parameters, such as blood pressure characteristics, in each part of the circulatory system based on fluid volume depletion and replenishment in a body portion of a subject. This is accomplished by applying a known pressure to a body region in increasing increments to thereby force blood volume depletion from the body region in a step-wise fashion through each vessel type. Fluid volume depletion and/or replenishment is then tracked or measured for each compartment type in the pressurized area. Pressure and volume data are then referenced against one another such as by graphing or otherwise recording the data. If plotted, the series of slope changes reveal the characteristic blood pressure state for each vessel type (Davis, paragraphs 51 and 52, emphasis added).

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"One important element of certain aspects of the [Davis] invention is the identification of the characteristic pressure states, or identities, for each vessel type, and the state transition boundaries that exist between fluid compartments of the subject. The [Davis] invention makes use of the volume and pressure states transitions to identify the characteristic pressure P (i) (see e.g., FIG. 7) for fluid compartments in the subject from pressure and volume data acquired noninvasively from the body region of a subject. It is the identification of the unique state transition boundaries for each fluid compartment which allows for determination of physiological parameters associated with each fluid compartment from further analysis of the acquired data." (Davis, paragraph 89, emphasis added)

The Davis reference specifically states that the Davis invention "is not dependent on oscillometric or pulsatile measurement methods...[the Davis] invention's lack of dependency on sensing the natural pulsations on the subject eliminates the time dependency on the occurrence of the naturally occurring pulsation for the measurement of physiologic parameters and allows for determination of physiological parameters in fluid compartments that are non-pulsatile or oscillometric in nature." (Davis, paragraphs 54 and 55, emphasis added). "Therefore, the [Davis] invention does not depend on naturally occurring pulsations or oscillations within the arteries of the subject for the measurement of physiologic parameters..." (Davis, paragraph 93, emphasis added)

It is respectfully submitted that Claim 1 is not anticipated by the Davis invention.

Claim 1 recites:

A process for measuring pressure buildup in one or more body compartments that encases muscular tissue, comprising the steps of:  
assessing a body compartment configuration; and,  
identifying the effect of pulsatile components on at least one dimension of the body compartment.

It is respectfully contended that the Davis reference and the instant invention are significantly different from one another. It is submitted that the Davis reference does not disclose every recited element in Claim 1, specifically, the Davis reference does not teach or suggest measuring pressure buildup in one or more body compartment by assessing a body

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compartment configuration and "identifying the effect of pulsatile components on at least one dimension of the body compartment." To the contrary, as explained above, the Davis reference repeatedly states that the Davis invention does not depend on oscillometric or pulsatile measurement methods for the measurement of physiological parameters, but rather uses the relationship of fluid volume versus pressure to identify how the volume/pressure state transition from one fluid compartment to the next is indicative of each compartment's physiological attributes. The pressure and volume data are obtained by applying a known pressure to a body region in increasing increments to thereby force blood volume depletion from the body region in a step-wise fashion through each vessel type.

In light of the above, independent Claim 1 is believed to fully distinguish from the Davis reference, and thus it is believed to be in condition for allowance. Because Claims 2-5 and 8-12 (as well as Claims 6 and 7) depend from Claim 1, these claims are also believed to be in condition for allowance.

Based on the above, reconsideration and withdrawal of the present rejection are respectfully requested.

**Rejection of Claims 6, 7 and 13-24 under 35 U.S.C. §103:**

The Examiner has rejected Claims 6, 7 and 13-24 under 35 U.S.C. § 103, as being unpatentable over Davis et al. in view of Mignot (U.S. 5,569,853). Specifically, the Examiner stated :

Davis teaches all the claimed subject matter except for mentioning specifically the means for mathematical manipulation of ultrasonic wave and means for capturing temporal reception of ultrasonic waves. Mignot teaches...means for mathematical manipulations of ultrasonic wave and means for capturing temporal reception of ultrasonic waves. Therefore it would have been obvious to an ordinary skill in the art (sic) at the time the invention was made to modify Davis's process, method, and apparatus for measuring pressure buildup in the blood vessels such that it includes means for mathematical manipulations of ultrasonic wave and means for capturing temporal reception of ultrasonic waves in order to minimize the number digital values to provide an enhanced image of the blood vessel network as taught by Mignot.

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It is respectfully contended that no reasonable combination of the Davis and Mignot references renders the instant invention obvious. As explained above in response to the Examiner's § 102 rejection, contrary to the Examiner's assertion, it is respectfully submitted that the Davis reference does not teach "all of the claimed subject matter with the exception of the means for capturing temporal reception of ultrasonic waves and the means for mathematical manipulation of ultrasonic waves." To the contrary, it is again submitted that the Davis invention is significantly different from the instant invention. The Davis reference provides means and methods for gathering physiological parameters, such as blood pressure characteristics, in each part of the circulatory system based on fluid volume depletion and replenishment in a body portion of a subject, this is accomplished by applying a known pressure to a body region in increasing increments to thereby force blood volume depletion/replenishment from the body region in a step-wise fashion through each vessel type. Further, in the Davis invention it is "the identification of the unique state transition boundaries for each fluid compartment which allows for the determination of physiological parameters associated with each fluid compartment by further analysis of the acquired data."

Independent Claim 13 recites:

An apparatus for measuring pressure build-up in one or more body compartments that encases muscular tissue, comprising:

- (a) a transmitting device for imparting ultrasonic waves into the one or more body compartments;
- (b) means for positioning the transducer adjacent to the one or more body compartments effective for imparting ultrasonic waves therein;
- (c) means for capturing reflections of the imparted ultrasonic waves and converting the reflected waves into electrical signals;
- (d) means for mathematically manipulating the electrical signals; and,
- (e) means for categorizing pressure build-up in the one or more body compartments from the mathematical manipulations.

It is again respectfully submitted that the Davis reference does not teach all of the claimed subject matter with the exception of the means for capturing temporal reception of ultrasonic waves and the means for mathematical manipulation of ultrasonic waves, that is recited in Claim 13. Therefore, it is respectfully contended that no combination of the Davis and

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Mignot references would result in the instant invention as recited in Claim 13. For this reason independent Claim 13 is believed to fully distinguish from the applied references, and in condition for allowance.

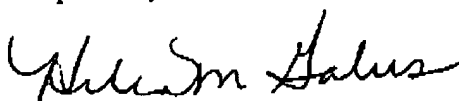
Because Claims 12-24 depend from what is believed to be an allowable base claim, Claim 13, they too are believed to be in condition for allowance. For the same or similar reasons Claims 6 and 7 are also believed allowable, further Claims 6 and 7 depend from what is believed to be an allowable Claim 1, for the reasons set forth above in response to the Examiner § 102 rejection, they are therefore also believed to be allowable by virtue of this dependency as well.

Based on the above, reconsideration and withdrawal of the instant rejection respectfully requested.

#### CONCLUSION

It is submitted that the Applicants have submitted new and unique Ultrasonic Apparatus And Method to Assess Compartment Syndrome. In view of the above, it is submitted that Claims 1-24 are in condition for allowance. Therefore, it is requested that a Notice of Allowance be issued at an early date.

Respectfully submitted,



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